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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,884	03/31/2004	Shoichi Kanayama	251157US2SX	4570

22850 7590 11/15/2010
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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

CWERN, JONATHAN

ART UNIT	PAPER NUMBER
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3737

NOTIFICATION DATE	DELIVERY MODE
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11/15/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/812,884	Applicant(s) KANAYAMA ET AL.	
	Examiner Jonathan G. Cwern	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-16,19,20,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-16,19,20,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/5/10 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 7-16, 19-20 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US 2003/0069491) in view of Unger et al. (US 5977538) and Chen et al. (US 2004/0042006).

Kruger discloses a non-invasive imaging apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30), light irradiation and waveguide means (18, 84) for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) at a plurality of wavelengths (2-12 centimeters, paragraph 4), a plurality of vertically and horizontally arrayed electroacoustic transducer elements with gaps between elements (24, 32, Figure 3), transmission means for transmitting Ultrasonic waves (52, 54), reception means for generating a reception signal from the ultrasonic waves (52, 56), signal processing means for generating volume data by processing a reception signal corresponding to acoustic waves generated in the subject by light radiated from the irradiation unit (46, 48), and signal processing means for generating volume data about a subject morphology by processing a reception signal corresponding to echoes generated in the subject upon transmission of the ultrasonic waves (US imaging system, 52). Kruger further discloses a waveguide (84) discretely arranged between arrayed electroacoustic transducer elements in a handheld unit (86-1 through 86-8; see also Figure 7), surrounded by eight elements. Kruger further discloses scanning means

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(scanning system, paragraph 37), accomplished by rotating the waveguides (18) and detector array (24) to multiple angular positions (paragraph 31) and further discloses generating a reception signal corresponding to acoustic waves generated by irradiation of the light (TACT system and receiver, 46 and 48), from electrical signals from a predetermined number of transducer elements (24, 32) near an end portion of a waveguide (Figure 1).

Kruger also refers to US Patent 5713356 filed by Kruger in the background section ([0011]-[0012]). Kruger describes the invention as an improvement on this patent, and states that the patent discloses methods for measuring relative time delays of the acoustic waves generated by a sequence of such pulses of electromagnetic radiation. While not explicitly stated, the improved invention would function in a similar way, using a sequence of pulses. At the very least, it would be obvious to one of ordinary skill in the art, at the time the invention was made, to have delivered the electromagnetic radiation in a sequence as it is an old and well known expedient in the art.

Kruger does not explicitly disclose using optical fiber for the waveguide means and does not explicitly disclose a plurality of waveguides in the handheld unit. Kruger et al. also fail to show the plurality of optical fibers arranged in the intervals between horizontally and vertically arrayed transducer elements and that each optical fiber is surrounded by four adjacent conversion elements, as well as multiplexing the output light.

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Unger et al. disclose an optoacoustic imaging system. Unger et al. teach that the optical fibers can be arranged horizontally, vertically, or in a circle, in between or around the transducer elements (column 5, lines 1-45 and Figures 3A-3F). This includes a configuration such that each optical fiber is surrounded by four adjacent conversion elements (see Figure 3F). Such configurations are old and well known in the art, and the benefits of such configurations are also well known. For example, one arrangement could allow for the lateral spatial resolution of the images produced to be improved, or one arrangement could be used to obtain more uniform and/or more powerful illumination. The specific configuration of the optical fibers and transducer elements is an obvious design choice which can be selected by one of ordinary skill in the art. While Kruger does not go into specific details of the optical delivery arrangement, Unger et al. teach a variety of arrangements for the light source which can provide light at multiple wavelengths (column 4, lines 35-52). Furthermore, Unger et al. also teach that their invention can sequentially excite different groups of transducers and their respective optical elements to improve the spatial resolution of the acoustic image (column 2, lines 54-59 and column 5, lines 15-60).

Optical fibers are a well-known waveguide means for infrared and visible light electromagnetic radiation. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger to use optical fiber as the waveguide means as taught by Unger et al., in order to investigate the subject properties at infrared and visible wavelengths. Furthermore, the exact number of elements surrounding the waveguide is an obvious design choice.

Chen et al. disclose a multiplex coherent Raman spectroscopy detector. Chen et al. teach an optical arrangement which uses an optical parametric oscillator to generate multiple wavelengths of light, with multiplexing components to allow the light to travel along the same path ([0040]-[0051]).

It would have been obvious to one of ordinary skill in the art, to have substituted an optical arrangement such as taught by Chen et al. in order to generate light at multiple wavelengths on a single optical axis, as it would be an obvious design choice. A variety of different optical arrangements are well known in the art, and it would be an obvious design choice to select any arrangement which will yield the desired results. This can simplify the device, reduce the size and cost of the system, speed up the diagnostic procedure, make the device easier for an operator to handle, or provide any other well known advantages.

As per claim 7, Kruger further discloses radiating light beams (electromagnetic radiation, see abstract) from not less than two optical fibers (at least eight waveguides, Figure 6A) whose end portions are spaced apart by not less than a predetermined distance.

As per claim 8, Kruger further discloses generating a reception signal corresponding to acoustic waves generated by irradiation of the light (TACT system and receiver, 46 and 48), from electrical signals from a predetermined number of transducer elements (24, 32) near an end portion of an optical fiber (waveguide, Figure 1).

As per claim 9 and 19, Kruger further discloses simultaneously radiating light (synchronized electromagnetic radiation, paragraph 16) from a plurality of end portions of optical fibers (waveguides, Figure 1-; eight positions, Figure 6).

As per claim 10, Kruger further discloses generating a reception signal from electrical signals (TACT system and receiver, 46 and 48), from a predetermined number of transducer elements (24, 32) near an end portion of an optical fiber (waveguide, Figure 1).

As per claims 11-12, and 20, Kruger further discloses alternately (separately) performing (Simultaneously, or as a separate imaging modality, paragraph 37) the irradiation of light and the transmission of ultrasonic waves.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Kruger to use separate electroacoustic conversion means as it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art, *Nerwin v. Erlichman*, 168 USPQ 177, 179. Furthermore, separate arrays of transducer elements would avoid the need for filtering of the two signals.

As per claim 13, Kruger further discloses forming a 2-dimensional image (paragraph 10). Furthermore, forming a 2-dimensional image from a 3-dimensional volume of data inherently requires selecting a single slice from the 3-dimensional volume.

As per claims 14 and 15, Kruger further discloses displaying (display, 50) living body function image data (TACT data, paragraph 37) and morphology image data

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(ultrasound image, paragraph 37), with said morphology image data superimposed on (overlaid, paragraph 37) said living body function image data on the display. Kruger does not explicitly disclose displaying the images side by side. It would have been obvious to a person having ordinary skill in the art at the time of the invention to display the images side by side, as it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japiske*, 86 USPQ 70.

Response to Arguments

Applicant's arguments filed 10/5//10 have been fully considered but they are not persuasive.

First, the examiner's previous position regarding sequential scanning still applies, as was addressed in the previous rejection: In regards to applicant's arguments that Kruger does not disclose sequentially irradiating the subject with light, examiner respectfully disagrees. Rotation of the waveguides to scan different portions of the breast is indeed a sequential scanning, or irradiation. The system rotates the light to irradiate different areas of the breast, and can be arranged to do so in a variety of different sequences, as illustrated in paragraphs [0039]-[0043]. Applicant argues that rotation of the waveguides "merely changes the location of the irradiation and corresponding reception". The examiner believes that changing the location does meet the claim limitation of "sequentially irradiating the subject".

In an effort to aid in advancing prosecution, the examiner would also note that Kruger also refers to US Patent 5713356 filed by Kruger in the background section

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([0011]-[0012]). Kruger describes the invention as an improvement on this patent, as it is now made to be smaller. Kruger states that the patent discloses methods for measuring relative time delays of the acoustic waves generated by a sequence of such pulses of electromagnetic radiation. Therefore, the improved invention would function in a similar way, using a sequence. Of course, Kruger does not discuss this in detail as the use of a sequence of pulses is an old and well known expedient in the art.

And furthermore, Unger et al. also teach that their invention can sequentially excite different groups of transducers and their respective optical elements to improve the spatial resolution of the acoustic image (column 2, lines 54-59 and column 5, lines 15-60).

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art
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